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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,216	06/13/2001	Robert E. Richard	12013/59001	4088

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EXAMINER	
TSOY, ELENA	
ART UNIT	PAPER NUMBER
1762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/879,216	RICHARD, ROBERT E.	
	Examiner	Art Unit	
	Elena Tsoy	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 23, 2007 has been entered.

Response to Amendment

Amendment filed on January 23, 2007 has been entered. Claims 3-6, 9-10, 12-15, 28-29, 31, and 33-36 have been cancelled. New claims 36-58 have been added. Claims 36-58 are pending in the application.

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claim 44 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 43. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Rejection to claim 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn due to cancellation of the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 37-39, 41-44, 46-48, 52, and 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu (US 6,203,551) in view of Sand (US 4,598,006).

Wu in view of Sand is applied here for the same reasons as set forth in paragraph 4 of the Office Action mailed on June 26, 2006. Note that claim does not recite that a first SCF and a second SCF are *different*.

As was discussed in paragraph 4 of the Office Action mailed on June 26, 2006, Wu teaches that after soaking stent 28 with the solution, the stent 28 is rapidly *dried* causing the polymer to **collapse** (claimed temporarily swelling), trapping a high concentration of the substance into the polymer's matrices (See column 9, lines 47-53). Obviously, drying SCF would also collapse the polymer, as required by Amendment.

As to claim 42, Wu teaches that stent may be made from metal and coated with a polymeric material (See column 1, lines 66-67; column 7, lines 10, 46-47; column 8, lines 6-8).

7. Claims 37-39, 41-44, 46-48, 52, and 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sand in view of Wu for the reasons, discussed above and for the reasons set forth in paragraph 5 of the Office Action mailed on June 26, 2006.

8. Claims 37-39, 41-44, 46-48, 52, and 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in view of Sand/Sand in view of Wu, further in view of Stack et al (US 5,527,337).

Wu in view of Sand/Sand in view of Wu are applied here for the same reasons as above.

Stack et al teach that treating a polymer stent with SCF to swell the polymer and removing the SCF under reduced pressure create very small pores in the polymer which can be filled with a drug containing solution under hydrostatic pressure (See column 12, lines 4-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have removed SCF from a swollen polymer coating of a stent in Wu in view of Sand/Sand in view of Wu thereby forming very small pores, and then added a solution of therapeutic in SCF under critical pressure with the expectation of providing the desired incorporation of therapeutic into the formed pores, since Stack et al teach that treating a polymer stent with SCF to swell the polymer and removing the SCF under reduced pressure create very small pores in the polymer which can be filled with a drug containing solution under hydrostatic pressure.

9. Claims 40, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in view of Sand/Sand in view of Wu/Wu in view of Sand further in view of Stack et al/Sand in view of Wu further in view of Stack et al/, and further in view of Mehta et al (US 6,627,246).

As to claims 40 and 49, Mehta et al teach that *paclitaxel* therapeutic agent (See column 8, line 29) is soluble in super critical carbon dioxide (See column 6, lines 65-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated paclitaxel therapeutic agent in Wu in view of Sand/Sand in view of Wu since Wu in view of Sand/Sand in view of Wu teach that any therapeutic agent soluble in SCF can be loaded into a polymer, and Mehta et al teach that paclitaxel therapeutic agent soluble in super critical carbon dioxide.

As to claim 48, Mehta et al teach that the therapeutic agent can be may be mixed with SCF to form a true solution or may be in a suspension of particles (See column 9, lines 35-50). It is well known that colloidal suspensions may be referred to as "colloidal solutions" because the extremely small particle size. Obviously swelled polymer would be able to incorporate the therapeutic agent from colloidal solutions because of the extremely small size of the agent.

10. Claims 45, 50, 51, 53, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in view of Sand/Sand in view of Wu/Wu in view of Sand further in view of Stack et al/Sand in view of Wu further in view of Stack et al/, and further in view of Allen et al (US 6,495,204).

The cited prior art is applied here for the same reasons as above. The cited prior art fails to teach that: (i) the medical device can be coated by spray-on deposition (Claim 45) using nozzle (Claim 50); (ii) collecting residual SCF and therapeutic (Claim 58).

As to (i), Allen et al teach that typically coating with the use of SCFs involves the application of one or more modifying agent by batch soaking in an enclosed chamber or includes processes based upon spraying from a pressurized chamber through a narrow nozzle (See column 1, lines 65-67). Upon spraying of the fluid onto the substrate, the supercritical fluid carrying the coating material leaves the high pressure environment and is exposed to a normal atmospheric environment (See column 2, lines 7-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used spray-on deposition in the cited prior art instead of a batch soaking in an enclosed chamber since Allen et al teach that coating with the use of SCFs can be typically done either by a batch soaking in an enclosed chamber or by spray-on deposition.

As to (ii), Allen et al further teach that SCF and a coating material can be removed and ***recycled*** for further use (See column 6, lines 60-62).

As to claim 51, Allen et al further teach that an injector 30 (with a nozzle) can be configured to inject the process fluids tangentially, perpendicularly, or at any other functional angle (claimed manipulating the nozzle to change the direction of the SCF flow). For example, a tangentially angled injector could be used in a chamber having two larger opposing regions, separated by a constricted medial region. Additionally, multiple injectors can be used to ensure that all surfaces of the non-equidimensional substrate can be appropriately modified. Alternatively, a perpendicular injector at close proximity to a substrate could be used to impregnate the substrate with higher pressure injections. In another embodiment, the processing chamber can utilize a treatment mixture comprised of the modifying agent and a carrier for applying the modifying agent, wherein the carrier is selected from the group consisting of supercritical fluid. See column 5, lines 48-63.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hossainy et al (US 6,860,946) is provided as an evidence to substantiate the theory that it would have been obvious to one having ordinary skill in the art to have collected and removed

therapeutic as required by the claims, since Hossainy et al teach, "The recycling of the coating substance can produce significant cost savings when an expensive therapeutic agent is being used" (See column 8, lines 1-5).

Response to Arguments

12. Applicants' arguments filed January 23, 2007 have been fully considered but they are not persuasive.

(A) Applicants argue that without waiving any of arguments submitted on September 12, 2006, especially that patents being cited against the claims are non-analogous, and, therefore, may not be used to reject the claims, that there are additional reasons as to why the claims are allowable over the cited patents. As to claims 37 and 52, they are patentable over each of the cited patents at least because none of them discloses or suggests "temporarily swelling the carrier coating with a supercritical fluid devoid of therapeutic prior to providing a supercritical fluid carrying a therapeutic." For instance, the portion of Stack relied upon in the Office action, col. 12 Ins. 4-10, does not address swelling a coating let alone temporarily swelling it as in the claims. Rather, the cited portion of Stack addresses the permanent creation of very small pores in a material that will comprise a stent. There is no coating in the example, and the material that swells is permanently swollen.

The Examiner respectfully disagrees with this argument. First of all, primary reference of Wu teaches that after soaking stent 28 with the solution, the stent 28 is rapidly **dried** causing the polymer to **collapse** (claimed temporarily swelling), trapping a high concentration of the substance into the polymer's matrices (See column 9, lines 47-53). Obviously, drying SCF would also collapse the polymer, as required by Amendment.

As to the Applicants arguments that patents being cited against the claims are non-analogous, the Examiner maintains reasons for rejection discussed in P10 (A) of the Final Office Action mailed on 10/23/2006.

(B) Applicants argue that claim 58 is patentable at least because it recites "removing residual therapeutic from the supercritical fluid after collecting the supercritical fluid." Hossainy does not disclose or suggest this step. The cited portion of Hossainy discusses recycling a liquid coating substance by capturing runoff in a reservoir and reusing the runoff without further

manipulation, see col. 7:60 - col. 8:5. Hossainy does not suggest the collection of a supercritical fluid nor does it suggest that further manipulation of what is collected is possible.

The Examiner respectfully disagrees with this argument. Hossainy et al is a *secondary* reference which is relied upon to show that the recycling of the coating substance can produce significant cost savings when an expensive therapeutic agent is being used (See column 8, lines 1-5). Obviously, the recycling of the coating substance would produce significant cost savings in *any* coating process when an expensive therapeutic agent is being used for coating. Therefore, it would have been obvious to one having ordinary skill in the art to have collected and removed therapeutic in primary references of Wu and Sand with the expectation of providing the desired significant cost savings when an expensive therapeutic agent is being used, as taught by Hossainy et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is 571-272-1429. The examiner can normally be reached on Monday-Thursday, 9:00AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 26, 2007